We claim

1. Substantially pure desloratadine having an HPLC purity greater than 99.5%, and having an absorbance less than 0.15 Au at 420 nm for a 5%w/v solution in methanol, which does not show a peak for an impurity at a relative retention time in the range from about 0.85 to about 0.99 (relative to desloratadine appearing at a retention time of 25±5 minutes) which is greater than the discard limit set at less than 0.025% of total area, when tested according to an HPLC method performed using a Hypersil BDS C_8 column (15 cm x 4.6 mm, 5 μm particle size) with the following parameters: Mobile phase: Buffer solution having a pH of about 3, methanol and acetonitrile in a volume ratio of 8:1:1.

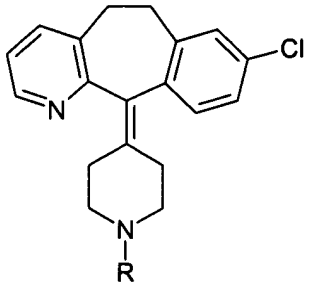
   Injection volume : 20μl
   Flow rate : 1.5 ml/minute
   Run time : 75 minutes
   Discard limit : Set at less than 0.025% of total area

2. Substantially pure desloratadine as claimed in claim 1, wherein (a) total impurities are not more than 0.5%; and (b) no individual impurity is greater than 0.1%.

3. Substantially pure desloratadine as claimed in claim 2, wherein the total impurities are less than 0.3%.

4. A substantially pure desloratadine of claim 1, 2 or 3 prepared by a process comprising acidic hydrolysis of a compound of **formula 3,** where R is selected from COR_1, $COOR_1$, wherein R_1 is selected from branched or linear alkyl containing 1 to 6 carbon atoms, cycloalkyl, alkenyl, alkynyl, aryl, aralkyl and their substituted analogs; by heating with a strong organic acid or a mineral acid for about 1 hour to about 24 hours, adjustment of pH of the hydrolysed reaction mixture to a pH

between the range of about 3 to about 5, optional treatment with an adsorbent, adjustment of pH of the reaction mixture to a pH of greater than about 9 and isolation of desloratadine.



Formula 3

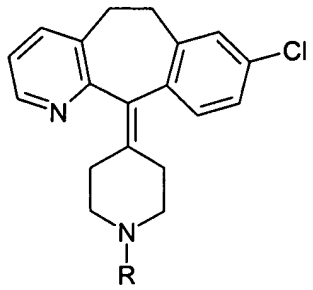
5. A substantially pure desloratadine of claim 4 prepared by a process comprising acidic hydrolysis of a compound of **formula 3,** by heating with an acid at a temperature between the range of ambient to about 150°C.

6. A substantially pure desloratadine of claim 4 further comprising recrystallization of desloratadine from a solvent system comprising a mixture of an alcohol and a hydrocarbon solvent.

7. A substantially pure desloratadine of claim 6 wherein alcohol is methanol and hydrocarbon solvent is cyclohexane.

8. A process for preparation of substantially pure desloratadine comprising acidic hydrolysis of a compound of **formula 3,** where R is selected from COR_1, $COOR_1$, wherein R_1 is selected from branched or linear alkyl containing 1 to 6 carbon atoms, cycloalkyl, alkenyl, alkynyl, aryl, aralkyl and their substituted analogs; and their substituted analogs, by heating with a strong organic acid or a mineral acid for about

1 hour to about 24 hours, adjustment of pH of the hydrolysed reaction mixture to a pH between the range of about 3 to about 5, optional treatment with an adsorbent, adjustment of pH of the reaction mixture to a pH of greater than about 9 and isolation of desloratadine.



Formula 3

9. A process as claimed in claim 8 wherein R is $COOR_1$ and R_1 is ethyl and the organic acid is methanesulfonic acid.

10. A process as claimed in claim 8 wherein R is $COOR_1$ and R_1 is ethyl and the mineral acid is sulphuric acid.

11. A process as claimed in claim 8, comprising acidic hydrolysis of a compound of **formula 3,** by heating with an acid at a temperature between the range of ambient to about 150°C.

12. A process as claimed in claim 11, comprising acidic hydrolysis of a compound of **formula 3,** by heating with an acid at a temperature between the range of about 60°C to about 110°C.

13. A process as claimed in claim 9, wherein the acidic hydrolysis is carried out by heating with metahnesulfonic acid for 5 to 15 hours at a temperature between the range of about 90°C to about 120°C.

14. A process as claimed in claim 10, wherein the acidic hydrolysis is carried out by heating with sulphuric acid for 1 to 5 hours at a temperature between the range of about 90°C to about 120°C.

15. A process as claimed in claim 8, wherein adsorbent is selected from charcoal, neutral or alkaline alumina, silica or fuller's earth.

16. A process as claimed in claim 8, comprising adjustment of pH of the reaction mixture to a pH between the range of about 4 to about 5, treatment with charcoal, adjustment of pH of the reaction mixture to a pH of about greater than 9 and isolation of desloratadine.

17. A process as claimed in claim 8, further comprising recrystallization of desloratadine from a solvent system comprising of two or more protic or aprotic solvents selected from water, alcohols, linear branched or cyclic hydrocarbons, aromatic hydrocarbons, ethers, ketones, nitriles, esters, and their halo or substituted analogs and the like.

18. A process as claimed in claim 8, further comprising recrystallization of desloratadine from a solvent system comprising a mixture of an alcohol and a hydrocarbon solvent.

19. A process as claimed in claim 18 wherein alcohol is methanol and hydrocarbon solvent is cyclohexane.

20. A process as claimed in claim 19, wherein the ratio of methanol:cyclohexane is 1:14 v/v.

21. A process as claimed in claim 8 for preparation of substantially pure desloratadine as described in claim 1, 2 or 3.